

5 117. (Twice Amended) A method for treating a subject having an abnormal mammalian cell proliferative disorder, comprising administering to the subject a fatty acid-anticancer compound conjugate composition in an amount which is at least about 30% on a molar basis greater than the maximum tolerated dose (MTD) in the subject for the unconjugated at least one anticancer compound.

9 33. (Twice Amended) A kit for administration of a fatty acid-anticancer compound conjugate composition to a subject, comprising
a container containing at least one fatty acid-anticancer compound conjugate, and
instructions for administering the at least one fatty acid-anticancer compound conjugate to subject in need of such treatment in an amount which is at least about 30% on a molar basis greater than the maximum tolerated dose (MTD) in the subject for the unconjugated at least one anticancer compound.

<Please add the following new claims 119-187:>

29 119. (New) The fatty acid-anticancer compound conjugate composition of claim 1, wherein the amount in the container is at least about 40% greater than the MTD for the unconjugated at least one anticancer compound.

30 120. (New) The fatty acid-anticancer compound conjugate composition of claim 1, wherein the amount in the container is at least about 75% greater than the MTD for the unconjugated at least one anticancer compound.

31 121. (New) The fatty acid-anticancer compound conjugate composition of claim 1, wherein the container is a container for intravenous administration.

32 122. (New) The fatty acid-anticancer compound conjugate composition of claim 12, wherein the taxane is paclitaxel or docetaxel.

33 123. (New) The fatty acid-anticancer compound conjugate composition of claim 1, wherein the conjugate is not encapsulated in a liposome.

34 124. (New) The fatty acid-anticancer compound conjugate composition of claim 1, wherein the fatty acid is docosahexaenoic acid.

3⁵ 125. (New) The method of claim 17⁵, wherein the amount of the fatty acid-anticancer compound conjugate composition administered is at least about 40% greater than the MTD for the unconjugated at least one anticancer compound.

3⁶ 126. (New) The method of claim 17⁵, wherein the amount of the fatty acid-anticancer compound conjugate composition administered is at least about 75% greater than the MTD for the unconjugated at least one anticancer compound.

3⁷ 127. (New) The method of claim 28⁸, wherein the taxane is paclitaxel or docetaxel.

3⁸ 128. (New) The method of claim 17⁵, wherein the conjugate is not encapsulated in a liposome.

3⁹ 129. (New) The method of claim 17⁵, wherein the fatty acid is docosahexaenoic acid.

4⁰ 130. (New) The kit of claim 33⁹, wherein the amount of the at least one fatty acid-anticancer compound conjugate is at least about 40% greater than the MTD for the unconjugated at least one anticancer compound.

4¹ 131. (New) The kit of claim 33⁹, wherein the amount of the at least one fatty acid-anticancer compound conjugate is at least about 75% greater than the MTD for the unconjugated at least one anticancer compound.

4² 132. (New) The kit of claim 33⁹, wherein the at least one fatty acid-anticancer compound conjugate is a taxane.

4³ 133. (New) The kit of claim 132⁴², wherein the taxane is paclitaxel or docetaxel.

4⁴ 134. (New) The kit of claim 33⁹, wherein the conjugate is not encapsulated in a liposome.

4⁵ 135. (New) The kit of claim 33⁹, wherein the fatty acid is docosohexaenoic acid.

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136. (New) A method for increasing the therapeutic index of anticancer compounds in a subject, comprising:

conjugating a fatty acid to an anticancer compound to form a fatty acid-anticancer compound conjugate; and

administering the fatty acid-anticancer compound conjugate to the subject, whereby the therapeutic index of the anticancer compound is improved relative to non-conjugated formulations of the anticancer compound, and wherein the fatty acid-anticancer compound conjugate is in an amount which is at least about 30% on a molar basis greater than the maximum tolerated dose (MTD) in the subject for the non-conjugated anticancer compound.

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137. (New) The method of claim ⁴⁶136, wherein the anticancer compound is a taxane.

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48 138. (New) The method of claim ⁴⁷137, wherein the taxane is paclitaxel or docetaxel.

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49 139. (New) The method of claim ⁴⁶136, wherein the conjugate is not encapsulated in a liposome.

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50 140. (New) The method of claim ⁴⁶136, wherein the fatty acid is a C8-C26 unbranched, naturally occurring fatty acid.

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51 141. (New) The method of claim ⁵⁰140, wherein the fatty acid is docosohexaenoic acid.

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52 142. (New) The method of claim ⁴⁶136, wherein the subject is human.

53 143. (New) A method for administering a fatty acid-taxane conjugate to a subject in need of such treatment, comprising infusing the conjugate in fewer than 3 hours.

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54 144. (New) The method of claim ⁵³143, wherein the conjugate is infused in 2 hours or less.

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55 145. (New) The injectable preparation of claim ¹⁰57, wherein the preparation comprises greater than about 7 mg/ml of the at least one fatty acid-taxane conjugate composition.

- 56 ~~146~~. (New) The injectable preparation of claim ~~57~~¹⁰, wherein the preparation comprises greater than about 8 mg/ml of the at least one fatty acid-taxane conjugate composition.
- 57 ~~147~~. (New) The injectable preparation of claim ~~57~~¹⁰, wherein the preparation comprises greater than about 10 mg/ml of the at least one fatty acid-taxane conjugate composition.
- 58 ~~148~~. (New) The injectable preparation of claim ~~57~~¹⁰, wherein the preparation comprises greater than about 15 mg/ml of the at least one fatty acid-taxane conjugate composition.
- 59 ~~149~~. (New) The injectable preparation of claim ~~57~~¹⁰, wherein the preparation comprises greater than about 40 mg/ml of the at least one fatty acid-taxane conjugate composition.
- 60 ~~150~~. (New) The injectable preparation of claim ~~57~~¹⁰, wherein the preparation comprises greater than about 60 mg/ml of the at least one fatty acid-taxane conjugate composition.
- 61 ~~151~~. (New) The injectable preparation of claim ~~57~~¹⁰, wherein the preparation comprises greater than about 100 mg/ml of the at least one fatty acid-taxane conjugate composition.
- 62 ~~152~~. (New) The injectable preparation of claim ~~57~~¹⁰, wherein the fatty acid is a C8-C26 unbranched, naturally occurring fatty acid.
- 63 ~~153~~. (New) The injectable preparation of claim ~~152~~⁶², wherein the fatty acid is docosohexaenoic acid.
- 64 ~~154~~. (New) The fatty acid-taxane conjugate composition of claim ~~70~~¹⁴, wherein the amount of the at least one fatty acid-taxane conjugate is greater than about 7 mg/ml.
- 65 ~~155~~. (New) The fatty acid-taxane conjugate composition of claim ~~70~~¹⁴, wherein the amount of the at least one fatty acid-taxane conjugate is greater than about 8 mg/ml.
- 66 ~~156~~. (New) The fatty acid-taxane conjugate composition of claim ~~70~~¹⁴, wherein the amount of the at least one fatty acid-taxane conjugate is greater than about 10 mg/ml.

- 67¹⁴ 157. (New) The fatty acid-taxane conjugate composition of claim ¹⁴70, wherein the amount of the at least one fatty acid-taxane conjugate is greater than about 15 mg/ml.
- 68¹⁴ 158. (New) The fatty acid-taxane conjugate composition of claim ¹⁴70, wherein the amount of the at least one fatty acid-taxane conjugate is greater than about 40 mg/ml.
- 69¹⁴ 159. (New) The fatty acid-taxane conjugate composition of claim ¹⁴70, wherein the amount of the at least one fatty acid-taxane conjugate is greater than about 60 mg/ml.
- 70¹⁴ 160. (New) The fatty acid-taxane conjugate composition of claim ¹⁴70, wherein the amount of the at least one fatty acid-taxane conjugate is greater than about 100 mg/ml.
- 71¹⁴ 161. (New) The fatty acid-taxane conjugate composition of claim ¹⁴70, wherein the fatty acid is a C8-C26 unbranched, naturally occurring fatty acid.
- 72¹⁴ 162. (New) The fatty acid-taxane conjugate composition of claim ¹⁴70, wherein the fatty acid is docosohexaenoic acid.
- 73¹⁷ 163. (New) The fatty acid-taxane conjugate composition of claim ¹⁷82, wherein the concentration of Cremophor is between about 9.6% and about 49.7% (vol/vol).
- 74¹⁸ 164. (New) The fatty acid-taxane conjugate composition of claim ¹⁸84, wherein the ratio of the weight of the at least one fatty acid-taxane conjugate and volume of the surfactant is at least about 60 mg/ml.
- 75¹⁸ 165. (New) The fatty acid-taxane conjugate composition of claim ¹⁸84, wherein the ratio of the weight of the at least one fatty acid-taxane conjugate and volume of the surfactant is at least about 70 mg/ml.
- 76¹⁸ 166. (New) The fatty acid-taxane conjugate composition of claim ¹⁸84, wherein the ratio of the weight of the at least one fatty acid-taxane conjugate and volume of the surfactant is at least about 80 mg/ml.
- 77¹⁸ 167. (New) The fatty acid-taxane conjugate composition of claim ¹⁸84, wherein the ratio of the weight of the at least one fatty acid-taxane conjugate and volume of the surfactant is at least about 90 mg/ml.

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⁷⁸168. (New) The fatty acid-taxane conjugate composition of claim ¹⁸84, wherein the fatty acid is a C8-C26 unbranched, naturally occurring fatty acid.

⁷⁸169. (New) The fatty acid-taxane conjugate composition of claim ⁷⁸168, wherein the fatty acid is docosahexaenoic acid.

¹⁸170. (New) The fatty acid-taxane conjugate composition of claim ¹⁸84, wherein the taxane is paclitaxel or docetaxel.

²¹171. (New) The fatty acid-taxane conjugate composition of claim ²¹94, wherein the solvent is ethanol.

⁸¹172. (New) The fatty acid-taxane conjugate composition of claim ⁸¹171, wherein the solvent and the surfactant are present in a ratio of about 1:1.

²²173. (New) The fatty acid-taxane conjugate composition of claim ²²97, wherein the ratio of the weight of the at least one fatty acid-taxane conjugate and volume of the solvent is at least about 50 mg/ml.

²²174. (New) The fatty acid-taxane conjugate composition of claim ²²97, wherein the ratio of the weight of the at least one fatty acid-taxane conjugate and volume of the solvent is at least about 60 mg/ml.

²²175. (New) The fatty acid-taxane conjugate composition of claim ²²97, wherein the ratio of the weight of the at least one fatty acid-taxane conjugate and volume of the solvent is at least about 70 mg/ml.

²²176. (New) The fatty acid-taxane conjugate composition of claim ²²97, wherein the ratio of the weight of the at least one fatty acid-taxane conjugate and volume of the solvent is at least about 100 mg/ml.

²²177. (New) The fatty acid-taxane conjugate composition of claim ²²97, wherein the fatty acid is a C8-C26 unbranched, naturally occurring fatty acid.

⁸⁷178. (New) The fatty acid-taxane conjugate composition of claim ⁸⁷177, wherein the fatty acid is docosahexaenoic acid.

- ⁸⁹179. (New) The fatty acid-taxane conjugate composition of claim ²²97, wherein the taxane is paclitaxel or docetaxel.
- ⁹⁰180. (New) The fatty acid-taxane conjugate composition of claim ²⁶108, wherein the solvent and the surfactant are present in a ratio of about 1:1.
- ⁹¹181. (New) The fatty acid-taxane conjugate composition of claim ²⁷110, wherein the amount of the at least one fatty acid-taxane conjugate is least about 40 mg/ml.
- ⁹²182. (New) The fatty acid-taxane conjugate composition of claim ²⁷110, wherein the amount of the at least one fatty acid-taxane conjugate is least about 50 mg/ml.
- ⁹³183. (New) The fatty acid-taxane conjugate composition of claim ²⁷110, wherein the amount of the at least one fatty acid-taxane conjugate is least about 60 mg/ml.
- ⁹⁴184. (New) The fatty acid-taxane conjugate composition of claim ²⁷110, wherein the amount of the at least one fatty acid-taxane conjugate is least about 100 mg/ml.
- ⁹⁵185. (New) The fatty acid-taxane conjugate composition of claim ²⁷110, wherein the fatty acid is a C8-C26 unbranched, naturally occurring fatty acid.
- ⁹⁶186. (New) The fatty acid-taxane conjugate composition of claim ²⁷110, wherein the fatty acid is docosahexaenoic acid.
- ⁹⁷187. (New) The fatty acid-taxane conjugate composition of claim ²⁷110, wherein the taxane is paclitaxel or docetaxel.
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